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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,219	06/23/2003	Thomas H. Turpen	LSBC-0087-CN09B	3972

27860 7590 03/09/2006

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EXAMINER

RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 03/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.		Applicant(s)	
	10/602,219		TURPEN ET AL.	
	Examiner		Art Unit	
	Delia M. Ramirez		1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 December 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6,8 and 9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 June 2003 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>9/17/04, 4/8/05</u> | 6) <input checked="" type="checkbox"/> Other: <u>alignments</u> |

DETAILED ACTION

Status of the Application

Claims 1-6 and 8-9 are pending.

Applicant's election of Group V, claims 1-6 and 8-9 drawn in part to a polynucleotide comprising SEQ ID NO: 11 or encoding the polypeptide of SEQ ID NO: 12, vectors, and virus particles comprising said polynucleotide, and a plant cell comprising said polynucleotide, in a communication filed on 12/15/2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicant's amendment canceling claims 7, 10-18 in a communication filed on 12/15/2005 is acknowledged.

Specification

1. The Brief Description of the Drawings section on page 19 is objected to due to the recitation of "Figure 12..." and "Figure 13..." for the following reasons. For consistency with the numbering of the drawings, it is suggested that the description of the drawings be amended to indicate "Figures 12-1 through 12-3" and Figures "13-1 through 13-2", or similar. Appropriate correction is required.
2. The specification is objected for not complying with sequence rules. While Figure 5 displays several sequences, neither the drawings nor the Brief Description of the Drawings indicate the corresponding sequence identifiers. Applicant is required to insert the corresponding sequence identifiers in the Brief Description of the Drawings or, in the alternative, amend the drawings to include the sequence identifiers in front of each sequence. See particularly 37 CFR 1.821(d). Appropriate correction is required.

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3. The specification is objected to since the reference to prior applications indicated in the first paragraph of the specification does not contain the current status of all nonprovisional parent applications to which priority is claimed. See particularly, U.S. Application No. 09/933059, 09/626127, and 09/316572. Appropriate correction is required (MPEP 201.11).

Priority

4. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/993,059 filed on 11/13/2001, 09/626,127 filed on 07/26/2000, 09/316,572 filed on 05/21/1999, 08/324,003 filed on 10/14/1994, 08/176,414 filed on 12/29/1993, 07/997,733 filed on 12/30/1992, 08/184,237 filed on 01/19/1994, 07/923,692 filed on 07/31/1992, 07/600,244 filed on 10/22/1990, 07/310,881 filed on 02/17/1989, 07/160,766 filed on 02/26/1988, and 07/160,771 filed on 02/26/1988, 07/641,617 filed on 01/16/1991, 07/737,899 filed on 07/26/1991, 07/739,143 filed on 08/01/1991, 07/347,637 filed on 05/05/1989, 07/363,138 filed on 06/08/1989, 07/219,279 filed on 07/15/1988, and 07/739,143 filed on 08/01/1991.

5. SEQ ID NO: 11-12 appear to have been first disclosed in U.S. Application No. 09/993059, filed on 11/13/2001.

Information Disclosure Statement

6. The information disclosure statements (IDS) submitted on 9/17/2004 and 4/8/2005 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Objections

7. Claims 1-6 and 8-9 are objected to as being directed to non-elected subject matter (i.e., the polynucleotides of SEQ ID NO: 3, 5, 7, 9, 13, 15, 17, 19, 31, 32, polynucleotides encoding the polypeptides of SEQ ID NO: 4, 6, 8, 10, 12, 14, 16, 18, 20, and plants comprising the polynucleotides of SEQ ID NO: 3, 5, 7, 9, 11, 13, 15, 17, 19, 31, 32). For examination purposes, it will be assumed that the instant claims are directed to the polynucleotide encoding the polypeptide of SEQ ID NO: 12, the polynucleotide of SEQ ID NO: 11, vectors and plant cells comprising said polynucleotides. Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 8-9 are indefinite due to the fact that they depend upon a canceled claim (i.e., claim 7). For examination purposes, the limitations recited in claim 7 will be included in claims 8-9 to the extent they relate to the elected subject matter. Correction is required.

Claim Rejections - 35 USC § 101

11. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

12. Claims 1, 6, 8-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

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Claims 1, 6 and 8-9, as written, do not sufficiently distinguish over nucleic acids and plant cells as they exist naturally because the claims do not particularly point out any non-naturally occurring differences between the claimed products and the naturally occurring products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See *Diamond v. Chakrabarty*, 447 US 303, 206 USPQ 193 (1980). The claims should be amended to indicate the hand of the inventor, e.g., by insertion of “isolated” or “purified” as taught by Example 11 of the specification. See MPEP 2105.

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 8-9 are rejected under 35 U.S.C. 102(b) as being anticipated by Desnick et al. (U.S. Patent No. 5356804, issued 10/18/1994; cited in the IDS). Claim 8 is directed to a polynucleotide encoding a polypeptide comprising SEQ ID NO: 12. Claim 9 is directed in part to a plant cell which expresses a polypeptide comprising SEQ ID NO: 12. Desnick et al. teach cloning and expression of human α -galactosidase A. The human α -galactosidase A of Desnick et al. comprise all of the polypeptide of SEQ ID NO: 12. Desnick et al. teach the cDNA encoding the α -galactosidase A (Figure 1A-1C) and plant cells transformed with plasmids containing the cDNA (column 15, lines 20-40). The cDNA of Desnick et al. (1393 nucleotides long) comprises all of SEQ ID NO: 11 (1266 nucleotides long) except for one mismatch at position 1257 of SEQ ID NO: 11 (silent mutation). See attached alignments. Therefore, the teachings of Desnick et al. anticipate the instant claims as written.

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Double Patenting

15. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

16. Claims 1-6 and 8-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 and 8-9 of copending Application No. 10/984389. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Conclusion

17. No claim is in condition for allowance.

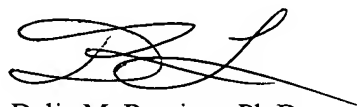
18. The cited U.S. patents and patent application publications are available for download via the Office's PAIR. As an alternate source, all U.S. patents and patent application publications are available on the USPTO web site (www.uspto.gov), from the Office of Public Records and from commercial sources.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (571) 272-0928. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

A handwritten signature in black ink, appearing to be 'DL' with a long horizontal stroke extending to the right.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
March 2, 2006